REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1, 4, 5, 7-9, 12, 19, 20, 26 and 27 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 1, 4, 6, 7, 10 and 12 have been rejected under 35 U.S.C. §102(b) as being anticipated by Nass-Arden et al., *Mol. Reprod. Dev.* (1990). This rejection is obviated by the amendment of claim 1 to (1) incorporate the feature of claim 28, (2) recite "increasing spermatozoa motility during the up to two hours of treatment", which recitation the examiner found to be previously absent from the claims, and (3) recite that the spermatozoa is from an oligospermic, asthenospermic, teratospermic or oligoasthenospermic patient (support found on page 13, last five lines). Even though the Examples in the specification do not show a time course of stimulation of sperm motility, the fact that motility was measured at exactly 2 hours of treatment and was significantly increased versus the control at that time point clearly indicates that the motility was increased during the first two

hours, as would be well recognized and understood by those of ordinary skill in the art.

Nass-Arden discloses increased motility of ram sperm relative to the control only after two hours of treatment with quercetin. Furthermore, there is no disclosure of treatment of human sperm for use in human fertility or ART. Accordingly, Nass-Arden cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1, 4-10, 12 and 19-29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Nass-Arden in view of Vlahos et al., *J. Biol. Chem.* (1994) and Bonjouklian et al., US Patent 5,378,725. This rejection is respectfully traversed.

Claim 1 is amended to recite "treating human seminal liquid comprising spermatozoa for up to two hours with an amount of a phosphatidylinasitol-3 kinase (PI3K) inhibitor sufficient to increase spermatozoa motility, thereby increasing spermatozoa motility during the up to two hours of treatment". Contrary to the examiner's assertion that treating the sperm for a particular amount of time is deemed merely a matter of judicious selection and routine optimization, which would be well within the purview of the

skilled artisan, Nass-Arden instead teaches one of ordinary skill in the art away from treating with a PI3K inhibitor for no more than two hours because the results in Fig. 1 of Nass-Arden clearly shows that treatment with quercetin for less than two hours gave "reduced" sperm motility compared to control cells not treated with quercetin. Therefore, one of ordinary skill in the art would only be taught from the disclosures of Nass-Arden to treat with quercetin for more than 2 hours; otherwise, the absence of quercetin (control/no treatment) would provide better sperm motility than treatment with quercetin during the first two hours. Accordingly, one of ordinary skill in the art would be motivated to optimize the result effective variable of time of treatment only in a range extending beyond 2 hours. Therefore, there is no *prima facie* case of obviousness.

Furthermore, Nass-Arden only studied the effect of quercetin on sperm motility in normal ram sperm. Neither Nass-Arden nor the secondary references of Vlahos and Bonjouklian teach or suggest what the effect of a PI3K inhibitor such as quercetin would have on human sperm from oligospermic, asthenospermic, teratospermic or oligoasthenospermic patients. Applicants have surprisingly and unexpectedly discovered in Example 1 that PI3k inhibitor stimulation of the progressive motility of human sperm is more

pronounced the more serious the sperm pathology of the patient, such as in oligospermic, asthenospermic, teratospermic or oliogoasthenospermic patients (specification, page 13, last five lines). Thus, claim 1 as amended, simply cannot be made obvious by a combination of Nass-Arden and Vlahos and Bonjouklian.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By /ACY/
Allen C. Yun
Registration No. 37,971

ACY:pp
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\S\SERO\Luconi1\pto\2006-12-19amd after final.doc